WASHINGTON, DC—On April 2, 2009, the House of Representatives passed by a vote of 298 to 112 H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, of which Congressman Joe Sestak (PA-07) was a co-sponsor. The Act now awaits President Obama's signature. The Family Smoking Prevention and Tobacco Control Act authorizes the Food and Drug Administration (FDA) to regulate the sale and distribution of tobacco products—including access to, advertising, and promotion of these products—if the agency determines that the regulations would be "appropriate to protect the public health."

"As a father, it is of upmost importance to me that we discourage teenage smoking," said Congressman Sestak. "By limiting marketing to children and removing tobacco products specifically marketed to kids we can prevent some of the 3,500 children who try cigarettes for the first time every day from falling into an addictive and dangerous habit."

The bill requires tobacco manufacturers to disclose the contents of and list harmful ingredients in their current products and prior to introducing new products. It also limits the marketing of modified risk tobacco products, products typically marketed as "light," "mild," or "low." These products can only have described as modified risk if there is evidence suggesting it significantly reduces the risk of tobacco-related disease to individuals. The bill requires the FDA to examine ways to regulate products that promote abstinence from tobacco use, reductions in consumption, and reductions in the harm associated with tobacco use. This would facilitate expanded health insurance coverage of effective cessation treatments for those addicted to tobacco.

The bill fully funds FDA tobacco activity through user fees on tobacco product manufacturers. However, the Congressional Budget Office has determined that the bill would reduce federal tobacco tax receipts by $743 million over the next 10 years because its enactment is projected to reduce smoking, while it will save $79 million over that time in reduced Medicaid costs. To ensure Congress funds this new legislation, the Federal Retirement Reform Act (which the House passed yesterday) will be appended to the bill.

This bill, which was endorsed by the major Federal employee unions, would create a Roth IRA program in the Federal Thrift Savings Program, give retirees credit for unused sick leave, make technical changes for eligibility for and reentry into the Federal Employee and Civil Service Retirement Systems. The bill also calls for a study to determine the costs of implementing a similar retirement program for the Uniformed Services. These actions would have a net positive effect on tax revenue and would account for any lost revenue due to decreased tobacco tax

receipts.

Specific Provisions of HR1256, The Family Smoking Prevention and Tobacco Control Act

Restrictions on Sale of Tobacco Products
The measure authorizes the FDA to issue regulations restricting the sale and distribution of tobacco products, including access to, advertising, and promotion of those products, if the agency determines that the regulations would be “appropriate to protect the public health.” The measure specifically authorizes the FDA to impose restrictions on the advertising and promotion of tobacco products within retail establishments that limit admittance to persons over 18 years of age.

Prohibition on Flavored Cigarettes
The measure prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than tobacco. The measure exempts menthol-flavored cigarettes, however, from this prohibition. The restriction would apply to such flavors as “Mandalay Lime,” “Warm Winter Toffee,” “Mocha Taboo,” and “Midnight Berry.” A cigarette would not be determined to have a prohibited characterizing flavor based solely on the presence of an ingredient in the product or its smoke. The bill also requires a study on the impact of menthol in cigarettes on children.

Tobacco Product Standard
The bill allows the FDA to adopt a product standard for tobacco products if it determines that such a standard is appropriate for the protection of public health. The standard could include provisions to alter (but not eliminate) nicotine yields, to reduce or eliminate other constituents or harmful components, and labeling of the tobacco product.

The measure requires the FDA to review periodically, in consultation with other federal agencies, the product standards, and consider new medical, scientific, or other technological information.

Notification & Recall of Tobacco Products
The bill authorizes the FDA to make public service announcements relating to tobacco products

if those products present an “unreasonable risk of substantial harm,” and notification was the “most practicable means available to eliminate the unreasonable risk.” Under the bill, the FDA could recall a tobacco product if it contains a defect that would cause “serious adverse health consequences or death” and is not normally contained in tobacco products on the market.

Submission & Publication of Health Information
Content Descriptions
The measure requires, within six months of enactment, submission to the FDA of ingredients, compounds, substances, and additives by brand of cigarettes. It also requires a description of the content, delivery, and form of nicotine, as well as documents developed after enactment relating to health, toxicological, behavioral, or physiologic effects of tobacco products. This information would be required of all current and future tobacco products.

Written Notice of New Additive
The measure requires manufacturers to submit a written notice to the FDA at least 90 days prior to marketing if the manufacturer adds a new additive to its product or increases the amount of an additive. It also requires a written notice at least 60 days prior to marketing if a tobacco manufacturer eliminates or decreases an existing additive.

List of Harmful Ingredients
The bill requires the FDA, within three years of the legislation’s enactment and annually thereafter, to publish in an “easily available and understood format” a list of harmful and potentially harmful constituents in each brand. The measure requires the FDA to also conduct consumer research to ensure that publication of the list is not misleading. After five years, the agency would report to Congress on the results of the research, and provide a recommendation on whether or not to revise the list.

Registration of Tobacco Manufacturers
The bill mandates the registration of every entity that “owns or operates in any state any establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products.” The measure extends the requirement to foreign establishments. Once registered, every establishment would be subject to an inspection by the FDA once every two years.

Adulterated Tobacco Products
The measure establishes specific guidelines for determining whether tobacco products are

adulterated. “Filthy, decomposed, or otherwise contaminated substances in tobacco products, the preparation of such products, or the packaging of such products will cause them to be deemed adulterated.” Tobacco products held under unsanitary conditions or manufactured, packed, or stored in violation of good manufacturing practices would also be deemed adulterated. In addition, a product would be deemed adulterated if the manufacturer of it fails to pay required user fees, or if it does not meet the product standards established for the product.

Manufacturers Records on Tobacco Products

The measure authorizes the FDA to require tobacco manufacturers and importers to establish and maintain records and submit them to the agency, to ensure that tobacco products are not adulterated or misbranded. The FDA could also require manufacturers and importers to report serious unexpected adverse reactions caused by the use of a tobacco product.

Application for Review

The bill requires premarket review for all new tobacco products entering the market, unless the FDA determines that the product is “substantially equivalent” to an existing product. The measure defines substantial equivalence as having the same characteristics as a marketed product, or having “different characteristics, but [it] does not raise different public health questions.”

Application Content Requirements

The measure requires each application to contain all information published or known to the applicant relating to studies on the health risks of the product. The application would also be required to include a listing of ingredients; how the product is operated or used; a description of the methods employed to manufacture a product; and samples of the product and the product’s proposed labeling.

Denial of an Application

The bill requires the FDA, within 180 days, to make a determination of whether to allow the new product to enter the market or deny the application. The FDA could deny the application if the agency finds that the applicant has not shown that marketing of the product would be appropriate for the protection of the public health, or that the making of the product did not conform to good manufacturing practices, or if the labeling is false or misleading.

Modified Risk Tobacco Products

Labeling

The bill bars the selling or distributing of a modified-risk tobacco product without having obtained an order pertaining to the product from the FDA. The measure defines this as labeling or advertising that states or implies that the product presents a reduced risk of tobacco-related disease; or that uses the words “light,” “mild,” or “low.”

Authorizing Commercial Marketing
The measure provides that the FDA must issue an order so that a product may be commercially marketed. This order would be issued only if the agency determines that the applicant has demonstrated that the product will significantly reduce harm and the risk of tobacco-related disease to individual users.

Regulations & Guidelines
The bill requires the FDA, within two years of enactment, to issue guidance or regulations on the scientific evidence required for assessment and ongoing review of modified-risk tobacco products. The FDA would develop those regulations or guidelines in consultation with the Institute of Medicine.

Judicial Review
The measure allows any individual adversely affected by an FDA regulation relating to performance standards or premarket review to file, within 30 days, a petition for judicial review with a federal court of appeals. The measure clarifies that the remedies would be in addition to, not in lieu of, any other remedies provided by current law. Judgment by the appellate court would be final, subject to review by the Supreme Court.

Testing & Reporting Regulations
The bill requires the FDA, within 36 months of enactment, to issue regulations that mandate the testing and reporting of tobacco product smoke constituents, ingredients, and additives that the agency has determined should be tested in order to protect public health. The measure specifically allows the FDA to require the disclosure of the test results relating to tar and nicotine in labeling or advertising.

Compliance of Small Tobacco Manufacturers
The measure allows the FDA to delay testing and reporting requirements for four years. The FDA could also delay the deadline for testing and reporting on a case-by-case basis.

Scientific Advisory Committee
The bill establishes a 12-member advisory committee representing the public, tobacco growers, the health community, and tobacco manufacturers, with one member “solely and specifically” representing the interests of small manufacturers. The committee would provide advice and guidance to the FDA on the effects of alteration of the nicotine yields from tobacco products; the threshold level at which nicotine becomes addictive; and other health issues as requested by the agency.

Products Treating Tobacco Dependence
The bill requires the FDA to report to Congress within three years on ways to regulate and development products that promote abstinence from tobacco use, reductions in consumption, and reductions in the harm associated with tobacco use. This would facilitate expanded health insurance coverage of effective cessation treatments for those addicted to tobacco.

In order for this program to be compliant with PAYGO rules, H.R. 1804, the Federal Retirement Reform Act, which the House has already passed, has been appended to the legislation.

Specific Provisions in HR1804
-Automatic enrollment of newly-hired eligible federal employees and members of the uniformed services in the Thrift Savings Plan (TSP). The bill sets contributions of new participants at 3% of their basic pay. These participants would have the option of modifying the contribution percentage or completely declining enrollment.
-Authorizes the Federal Thrift Retirement Investment Board to establish a Roth contribution plan and self-directed investment options within the Thrift Savings Plan.
-Requires an annual report on the operations of the TSP.
-Gives retirees, or their survivors, credit for unused sick leave in calculating immediate annuity payments
-Exemption of certain CSRS repayments from the requirement that they be made with interest.
-Requires a study to determine the costs of implementing a similar retirement program for the Uniformed Services
-Increases indemnity allowances for widows and widowers of service personnel under the Survivor Benefit Plan offset. Currently, these payments are reduced dollar-for-dollar for payments under the Dependency and Indemnity Compensation plan. This bill increases the allowance to offset the reduction in payments to widows and widowers of service members.

Born and raised in Delaware County, former 3-star Admiral Joe Sestak served in the Navy for 31 years and now serves as the Representative from the 7th District of Pennsylvania. He led a series of operational commands at sea, including Commander of an aircraft carrier battle group

of 30 U.S. and allied ships with over 15,000 sailors and 100 aircraft that conducted operations in Afghanistan and Iraq. After 9/11, Joe was the first Director of "Deep Blue," the Navy's anti-terrorism unit that established strategic and operations policies for the "Global War on Terrorism." He served as President Clinton's Director for Defense Policy at the National Security Council in the White House, and holds a Ph.D. in Political Economy and Government from Harvard University. According to the office of the House Historian, Joe is the highest-ranking former military officer ever elected to the U.S. Congress.

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